Economic Impact of Health Care Regulation: An Example of Public Comment Documenting the Impact of a Hypothetical Regulation

The U.S. Department of Health and Human Services' Assistant Secretary for Planning and Evaluation (ASPE) and the Office of Management and Budget (OMB) have established an interagency committee to examine major Federal regulations governing the health care industry. The committee will examine the economic impact of major Federal regulations governing the health care industry, and will explore proposals for reducing regulatory burden, while maintaining the highest quality health care and other patient protections. Findings will be synthesized and included in a report to Congress.

The Government has requested public comment on the economic costs of regulation. Individuals and organizations making public comment are asked to provide an estimate of the economic impact of health care regulations, guidance documents, or paperwork requirements, and also to describe the methods they use to calculate the economic impact of the regulations.

On the following pages we provide an example, estimating the economic impact of a purely hypothetical regulation. This example is designed to give guidance regarding the types of information and documentation that are particularly useful to the committee.

We recognize that this example is fairly comprehensive and that different regulations may require different approaches, incorporate other economic costs and/or savings, or involve some nonquantifiable costs. For instance, in this example, there are no capital costs for buildings or equipment. Submissions should seek to quantify wherever possible the relevant costs, identify the sources of data, and explicitly state assumptions made and how any calculations were performed.

We welcome the submission of reports, spreadsheets, and supporting financial data. These data are being collected for the purpose of assessing the economic impact of major Federal health care regulations in accordance with House Appropriations Committee Report 108-636. Data submitted for this purpose will be protected to the extent allowed by Federal law.

Economic Impact of Health Care Regulation: An Example of Public Comment Documenting the Impact of a Hypothetical Regulation

Submitted by: United Pharmacy Association of the 50 States
234 Main Street
Washington, DC 20000
Phone: 202-999-9999
Please feel free to contact A. H. Hall, Director of Economic Studies, with any questions.

Background:

Every State-licensed pharmacy participating in the National Medicine Part Q prescription drug program is required to certify to the National Medicine Administration (NMA) once a month, using NMA Form B23, which Part Q drug plans the pharmacy accepts. NMA Form B23 is required to be signed by a pharmacist licensed in the State in which the pharmacy being certified is located, and the pharmacist must further certify that he/she has personal knowledge that the Part Q drug plans listed are in fact accepted.

The complete text of the regulation can be found at: 99 CFR Sections 413.343 et seq.

Original Justification for Regulation:

During the initial implementation of the National Medicine Act, 99 USC 1201 (2009), there were some reported problems of beneficiaries presenting their Part Q prescription drug cards to participating pharmacies and having the pharmacy reject them. Consumers complained that there was no good public source identifying Part Q pharmacy networks. Following an investigation by the appropriate House and Senate committees, the Act, as amended, directed the NMA to adopt appropriate regulations to address this perceived problem. The NMA promulgated 99 CFR Sections 413.343 et seq., which required every licensed pharmacy to individually certify which drug plans they participated in.

The Current Regulatory Burden and How It Can Be Reduced:

Our members do not object to the general thrust of the regulation; rather, their concern is with how the information is being collected. We note that in the intervening several years since the regulation became effective, our members have invested significantly in additional computer processing equipment and that the NMA now reports receiving very few complaints of this type. Our members believe that their investment in computers has significantly reduced these problems. In addition, some of our larger members report that all pharmacies in their chains are equipped to accept any Part Q card, regardless of where in the country a card is presented. Moreover, almost all of our members indicate that each of their stores is connected to the same computer system, and a single individual in a central location completing these forms has access to the identical information that a pharmacist in a particular location would have.

Economic Impact of Health Care Regulation: An Example of Public Comment Documenting the Impact of a Hypothetical Regulation

Recommended reform: Having one person centrally located in each chain to be responsible for completing a Statewide filing for all stores in a State, or even one form for the entire chain nationwide, would offer significant savings compared with the current policy of one-form-per-pharmacy.

Economic Burden of the Regulation:

On the next page we detail the savings we anticipate from our recommended change in the regulation. We estimate that our members are currently spending a minimum of $42,820,127 (annual aggregate amount) on compliance. This figure is based on the time it takes each pharmacy to have a highly paid pharmacist personally check the computer system and record the information on a monthly basis. Our assumptions are detailed on page 5. We believe that the same regulatory objectives can be achieved at a significantly lower cost by allowing chain store pharmacies to report at the State level or chain level, as appropriate. This proposed change in the regulation could save $39,759,946. The same regulatory goal can be achieved at a cost of just $3,060,181.

Economic Impact of Health Care Regulation: An Example of Public Comment Documenting the Impact of a Hypothetical Regulation

Estimated Cost of Compliance[1]

A. Pharmacy Chain	B. Number of Pharmacies	C. Average Time Per Form in Minutes	D. Pharmacist's Average Hourly Wage	E. Annual Savings
Chain A	4,589	72	$73.26	$4,200,138
Chain B	5,324	68	$76.46	$5,085,193
Chain C	3,595	84	$80.03	$4,172,492
Chain D	3,239	92	$80.76	$4,282,102
Chain E	2,601	54	$68.78	$1,851,485
Chain F	2,109	88	$77.13	$2,682,142
Chain G	2,654	82	$77.79	$3,323,856
Chain H	1,899	70	$77.25	$2,052,969
Chain I	1,143	58	$80.41	$1,064,340
Chain J	3,891	74	$69.96	$3,988,773
Chain K	490	82	$79.24	$631,473
Chain L	1,099	46	$83.27	$792,826
Chain M	1,502	36	$77.76	$802,128
Chain N	444	86	$83.85	$630,346
Chain O	941	52	$78.67	$733,696
Chain P	316	86	$71.22	$347,895
Chain Q	245	112	$69.66	$347,094
Chain R	1,210	72	$68.91	$1,107,288
Chain S	562	50	$76.17	$404,075
Chain T	222	66	$78.30	$213,550
Chain U	355	45	$77.95	$229,850
Chain V	653	66	$69.66	$574,841
Chain W	86	44	$76.41	$52,347
Chain X	241	44	$74.15	$148,257
Chain Y	77	36	$80.43	$40,790
Total Extra Costs of Compliance				**$39,759,946**

[1] See the accompanying table for explanation.

Economic Impact of Health Care Regulation: An Example of Public Comment Documenting the Impact of a Hypothetical Regulation

Sources of Information, Assumptions, and Notes:

Column A: Our source for the list of 25 largest pharmacies in the United States is *Today's Modern Pharmacy*, Vol. 36, page 29, 2014.

Column B: Our source for these data is *Today's Modern Pharmacy*, Vol. 36, page 29, 2014.

Column C: To calculate this number for each pharmacy in each chain, we assumed a fixed time of 10 minutes per form and 3 minutes per plan operating in the State in which the pharmacy was located. This is the average time across all pharmacies in each chain. These estimates for time to complete are the same values used by the National Medicine Administration when the initial regulation was proposed, and the OMB accepted them under the *Paperwork Reduction Act*.

Column D: This is the average hourly pharmacist's wage across each chain. Data for pharmacists at the State level were obtained from the U.S. Department of Labor, Occupational Employment Statistics, Occupational Employment and Wages, November 2013. See *http://www.bls.gov/oes/current.*

Column E: Prior costs of compliance were estimated as B*(C/60)*D*12. The estimate for savings is generated as [B*(C/60)*D*12]-[$100*(Number of States the Chain Operates in)]. The term [$100*(Number of States the Chain Operates in)] is our best estimate of the new costs of compliance. While we have not explicitly provided the number of plans operating in each State and the number of States each chain operates in, these values are available upon request.

Assumptions and Notes: Our estimate is based on the 25 largest pharmacy chains in the United States. These chain stores total 39,487 pharmacies, representing 92 percent of the chains with more than 5 stores. There are an estimated additional 18,999 pharmacies, and some of these are small chains with 5 or fewer locations. In order to be conservative, we have estimated no savings from these pharmacies. This is particularly conservative because these small chains are more likely to be family businesses with fewer sales for whom the costs of this regulation are particularly burdensome.